UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NADEZDA STEELE-WARRICK, individually and on behalf of all others similarly situated, Plaintiff vs. MICROGENICS CORPORATION AND THERMO FISHER SCIENTIFIC INC., Defendants	Hon. Vera M. Scanlon CASE 1:19-cv-06558-VMS **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT MICROGENICS CORPORATION'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED CLASS ACTION COMPLAINT AND TO STRIKE CLASS ALLEGATIONS**

Introduction

Based on a preliminary drug screen, the New York Department of Corrections and Community Supervision ("DOCCS") allegedly disciplined Plaintiff Nadezda Steele-Warrick for drug use during her incarceration for assault. Plaintiff insists she was not using illicit drugs, and because DOCCS performed her drug screen using a urinalysis analyzer supplied by Defendant Microgenics Corporation, she blames Microgenics for the discipline DOCCS meted out.

In her First Amended Class Action Complaint (the "Complaint"), Plaintiff alleges that Microgenics negligently caused her and a class of inmates to receive inaccurate drug screens. But Plaintiff concededly has no idea how or why Microgenics could be responsible for the allegedly inaccurate drug screens. In the Complaint, she muses that perhaps Microgenics negligently sold products for uses "inconsistent" with "applicable standards" or that it failed to train DOCCS employees about applicable standards or that its personnel negligently testified at disciplinary hearings. Plaintiff floats each of those concepts in cursory fashion without factual support.

Regardless, the Complaint is facially deficient, and Microgenics moves to dismiss Plaintiff's claim and to strike her class allegations for three reasons:

First, the Complaint fails to plausibly allege that Microgenics owed Plaintiff a duty. Plaintiff claims a duty arose out of Microgenics' contract to supply analyzers to DOCCS. But Plaintiff has no relationship with Microgenics, and under New York law, Microgenics' contractual undertaking to DOCCS did not give rise to a duty in tort owed directly to Plaintiff.

Second, even if Plaintiff had adequately alleged a duty of care, the Complaint fails to plausibly allege that Microgenics breached any purported duty. The Complaint offers various categories of potential breaches—negligent contracting, training, and testifying—without any supporting factual allegations to explain in what manner Plaintiff contends Microgenics breached a purported duty. Plaintiff's grab-bag conjecture does not support a viable claim for relief.

Third, even if the Complaint were construed to state a claim, Plaintiff's class allegations must be struck. Her proposed class necessarily includes inmates who received true positive drug-screen results, who suffered no injuries, and who therefore lack standing to sue. Moreover, Plaintiff's negligence claim simply is not amenable to classwide adjudication; numerous individual issues would govern the determination of whether DOCCS wrongly disciplined each class member for drug use, including whether the inmates' drug screens were accurate and whether DOCCS properly performed the screens and imposed discipline.

Factual Background

1. Plaintiff's incarceration

On May 8, 2015, Plaintiff was convicted of assault upon pleading guilty to "stabbing her mother-in-law with scissors during an altercation in their home." *People v. Steele-Warrick*, 177 A.D.3d 906, 906 (N.Y. App. Div. 2019). From June 2015 through May 2019, Plaintiff was incarcerated at Albion Correctional Facility. Compl. [ECF 31] ¶ 53.

Plaintiff claims that approximately one year into her incarceration she was admitted to a Family Reunion Program, which permits inmates to "spend overnights" with family members. Compl. ¶ 57. According to Plaintiff, DOCCS policy requires that inmates participating in the reunion program submit urine samples for drug-of-abuse screening. *Id.* ¶ 59. Specifically, samples must be given between two to ten days prior to a reunion-program visit, immediately prior to a visit, and immediately following a visit. *Id.* ¶ 59.

2. DOCCS's drug-of-abuse screening procedures for inmates

DOCCS personnel obtain drug-of-abuse urine samples from inmates after escorting them to "the facility infirmary, clinic or other appropriate area." 7 NYCRR § 1020.4(d)(1). In the process of obtaining samples, DOCCS personnel are required to ask each inmate if he or she "has been taking any medication in the past month." 7 NYCRR § 1020.4(d)(2).

For DOCCS facilities equipped with urinalysis apparatuses, DOCCS personnel perform the urinalysis drug screen at the facility. 7 NYCRR § 1020.4(f)(1). The DOCCS employee who performs the drug screen must "be appropriately trained in the use of the testing apparatus and shall precisely follow procedures recommended by the manufacturer for the operation of the testing apparatus." 7 NYCRR § 1020.4(f)(1)(iii).

If the initial screen returns a positive result, a "second test shall be performed on the same sample." 7 NYCRR 1020.4(f)(1)(iv). As to any inmate who receives a positive urine drug screen and who also reported taking medication at the time the sample was obtained, DOCCS must conduct an "inquiry . . . to medical personnel as to what medications the inmate has received in the past month which may lead to a positive result." 7 NYCRR § 1020.4(d)(2).

Prior to imposing discipline for drug use, DOCCS holds a hearing. 7 NYCRR § 253.6. The inmate may present a defense by, for example, explaining the positive drug screen, challenging the

drug-screen procedures, and contesting whether the screen was duly authorized. *Lahey v. Kelly*, 71 N.Y.2d 135, 144 (1987). The inmate has the right to submit evidence. 7 NYCRR § 253.6(c).

3. DOCCS's chosen method for *inmate* drug-of-abuse screening

DOCCS personnel conduct approximately 340,000 drug-of-abuse urine "scans" per year at 52 locations. Contract No. CC161458, Appendix C, [Ex. 1[1]] at 25.[2] To perform the scans, DOCCS uses "reagent tests." *Id.* That method, also referred to as the "immunoassay" method, "does not measure the amount of drugs in the urine directly, but instead measures the reaction of an enzyme to a specified drug." *Lahey v. Kelly*, 71 N.Y.2d 135, 140 (1987).

DOCCS has known for nearly 40 years that immunoassay manufacturers recommend that positive drug-screen results should be confirmed by an alternative scientific method, such as gas chromatography-mass spectrometry. *See Peranzo v. Coughlin*, 608 F. Supp. 1504, 1514 (S.D.N.Y. 1985) (discussing recommendations from a DOCCS immunoassay supplier that "positive results be confirmed by any of several chromatographic procedures").

Indeed, outside of the prison context, DOCCS uses those alternative methods. For instance, when a parolee screens positive for drug use via immunoassay, DOCCS requires a confirmation test "using the Gas Chromatography/Mass Spectrometry methodology to provide for a greater margin of accuracy." DOCCS Directive No. 9432 [Ex. 2] at 3.[3] And when screening its own employees, DOCCS insists that *both* the initial *and* the confirmatory tests are conducted "by gas

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[1] All exhibits are attached to the contemporaneously filed Declaration of Nathan J. Marcusen.

[2] The contract is integral to the Complaint, *see* Compl. ¶¶ 13–14, and may be considered at the Rule 12 stage, *Goel* v. *Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016); *Interpharm, Inc. v. Wells Fargo Bank, Nat'l Ass'n*, 655 F.3d 136, 141 (2d Cir. 2011).

[3] The Court may consider DOCCS directives at the Rule 12 stage. *E.g.*, *Young v. Corcoran*, 164 F. Supp. 3d 419, 421 (W.D.N.Y. 2016).

chromatography with mass spectrometry or an equivalent scientifically accepted method that provides quantitative data." DOCCS Directive No. 2115 [Ex. 3] at 6.

When screening prison inmates, however, DOCCS does not obtain confirmatory tests through chromatographic procedures. *E.g.*, DOCCS Directive No. 4937 [Ex. 4] at 5.

4. Microgenics' supply of drug-screen equipment to DOCCS

In September 2018, DOCCS hired Microgenics to supply Indiko Plus urinalysis analyzers and immunoassays for its 52 correctional facilities. Compl. ¶ 22. The Indiko Plus is a 510(k)-cleared medical device and is manufactured by Microgenics' corporate affiliate Thermo Fisher Scientific Oy, which is based in Finland. *See* 510(k) Substantial Equivalence Determination Decision Summary, 510(k) Number k110035, https://www.accessdata.fda.gov/cdrh_docs/reviews/K110035.pdf [Ex. 5] (last accessed Apr. 24, 2020) (identifying Thermo Fisher Scientific Oy as the 510(k) applicant).[4]

As noted in Microgenics' Indications for Use ("IFUs") for the CEDIA Buprenorphine II immunoassays used in the Indiko Plus analyzers (and as Plaintiff admits), a positive result from a urine drug-screen "provides only a preliminary analytical test result." 510(k) Substantial Equivalence Determination Decision Summary, 510(k) Number k163101, at 2 https://www.accessdata.fda.gov/cdrh_docs/reviews/K163101.pdf [Ex. 6] (last accessed Apr. 24,

[4] The Court may consider the publicly available FDA market-clearance documents for the subject products. *See, e.g.*, *Crespo v. S.C. Johnson & Son, Inc.*, 394 F. Supp. 3d 260, 266 n.3 (E.D.N.Y. 2019) (taking judicial notice of documents on EPA's website, including records pertaining to the subject product's EPA registration); *Tierney v. AGA Med. Corp.*, No. 4:11CV3098, 2011 WL 7400469, at *4 (D. Neb. Nov. 18, 2011) (taking judicial notice of "Instructions for Use" documents publicly available on FDA's website where said documents contained warnings against same adverse reaction suffered by plaintiff).

2020); see Compl. ¶ 34. The IFUs thus advise that, in the event of a positive screen, a "more specific alternative chemical method must be used to obtain a confirmed analytical result." *Id.* "Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method." *Id.* The IFUs further caution users that "[c]linical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used." *Id.*

Under its contract to supply DOCCS with analyzers and immunoassays, Microgenics also agreed to provide certain services, including preventive maintenance, training for DOCCS personnel, customer support, and testimony (via a support hotline) at disciplinary hearings. Compl. ¶¶ 27, 29; Contract No. CC161458, Appendix H, [Ex. 1] at 2–3.

5. Plaintiff's drug screen and contested drug charge

Plaintiff claims that following a reunion visit on April 14, 2019, she gave a urine sample to DOCCS personnel, who processed the sample using an Indiko Plus urinalysis analyzer. Compl. ¶¶ 60–61. The sample screened positive for "Suboxone/buprenorphine" (referred to collectively as "buprenorphine"). *Id.* ¶ 62. Plaintiff alleges that DOCCS personnel then rescreened the urine sample "as per protocol" and that it again screened positive for buprenorphine. *Id.* ¶¶ 63–64. Despite the two positive screens for buprenorphine, Plaintiff insists she "had not taken that substance, any substance known to trigger a positive result, or any other illicit substance." *Id.* ¶ 62. DOCCS did not confirm Plaintiff's presumptive positive result through a more specific alternative method, such as gas chromatography/mass spectrometry or liquid chromatography/tandem mass spectrometry. Compl. ¶¶ 60–64.

Plaintiff claims that after she screened positive for buprenorphine, DOCCS charged her with drug use. Compl. ¶ 66. She contested the charge, and she alleges that at the disciplinary

hearing, she testified she had not ingested buprenorphine, and her husband testified he had not given her any illegal substances. *Id.* ¶ 77. Plaintiff says she also submitted records "from her husband's doctor explaining that the false positive may have been triggered by a medication he had been prescribed." *Id.* ¶ 77. Plaintiff does not allege that DOCCS conducted any inquiry as to what medications she had received that might have caused a positive result. Nevertheless, a hearing officer found Plaintiff "guilty," and Plaintiff alleges that DOCCS sentenced her to eleven days in keeplock and thirty days loss of recreation, packages, and commissary privileges. *Id.* ¶¶ 78–79. According to the Complaint, DOCCS overturned the guilty finding in September 2019. *Id.* ¶ 88.

6. Plaintiff's Complaint

Plaintiff alleges that, by virtue of its contract with DOCCS, Microgenics owed her and other inmates a duty "to ensure that the Indiko Plus urinalysis analyzers were used in accordance with applicable standards and produced accurate and reliable test results." Compl. ¶ 109. The "applicable standards" to which Plaintiff refers are paraphrases of statements set forth in Microgenics' IFUs—that testing by immunoassay "should be used as an initial screen only" and that "confirmatory testing is required to verify any positive result." *Id.* ¶ 34.

Plaintiff claims that Microgenics breached its alleged duty to inmates by failing to ensure that Indiko Plus analyzers "yielded accurate and reliable test results"; by entering into a contract for the "use" of its analyzers that "was inconsistent with applicable standards"; by "failing to train DOCCS employees on applicable standards"; and by "testifying at disciplinary hearings . . . when [it] knew that the results were a preliminary screen only." Compl. ¶ 110.

Plaintiff asserts her negligence claim for herself and on behalf of a proposed class of "all persons . . . who received positive drug test results generated by Indiko Plus urinalysis analyzers while in DOCCS custody in 2019 and subsequently had those positive drug tests reversed,"

regardless of the drug for which the inmate tested positive and regardless of the immunoassay used to conduct the screen. Compl. ¶ 95. She seeks to recover alleged economic and noneconomic damages for the "serious discipline" she contends DOCCS meted out based on the purportedly inaccurate drug screens. *Id.* ¶ 112.

Procedural Background

Plaintiff filed her original class action complaint in November 2019. In response, Microgenics served a motion to dismiss and to strike the class allegations. Rather than serve an opposition to Microgenics' motion, Plaintiff filed her First Amended Class Action Complaint.

Law and Argument

I. The Complaint fails to state a plausible claim for relief and should be dismissed.

To withstand a motion to dismiss under Rule 12(b)(6), "'a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Concord Assocs., L.P. v. Entm't Props. Trust*, 817 F.3d 46, 52 (2d Cir. 2016) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2007)). The plausibility standard requires "'more than a sheer possibility that a defendant has acted unlawfully.'" *Galiano v. Fidelity Nat'l Title Ins. Co.*, 684 F.3d 309, 313 (2d Cir. 2012) (quoting *Iqbal*, 556 U.S. at 678). To meet the standard, a plaintiff must plead "'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Anyachebelu v. Brooklyn Hosp. Ctr.*, No. 16 Civ. 3159 (DLI) (VMS), 2017 WL 9511073, at *4 (E.D.N.Y. July 20, 2017) (quoting *Iqbal*, 556 U.S. at 678).

Although courts "construe the pleadings liberally, 'bald assertions and conclusions of law will not suffice.'" *Spool v. World Child Int'l Adoption Agency*, 520 F.3d 178, 183 (2d Cir. 2008) (quoting *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996)). Nor will a "'formulaic recitation of the elements of a cause of action.'" *Anyachebelu*, 2017 WL 9511073, at *4 (quoting *Twombly*, 550

U.S. at 555). Instead, the "factual allegations must be enough to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Port Dock & Stone Corp. v. Oldcastle Ne, Inc.*, 507 F.3d 117, 121 (2d Cir. 2007) (citing *Twombly*, 550 U.S. 544).

A. The Complaint fails to state a claim because it does not plausibly allege that Microgenics owed a duty directly to Plaintiff.

Under New York law, to establish a claim for negligence, "'a plaintiff must demonstrate (1) a duty owed by the defendant to the plaintiff, (2) a breach thereof, and (3) injury proximately resulting therefrom.'" *Pasternack v. Lab. Corp. of Am. Holdings*, 27 N.Y.3d 817, 825 (N.Y. 2016) (quoting *Solomon v. City of N.Y.*, 66 N.Y.2d 1026, 1027 (1985)).

"Absent a duty running directly to the injured person there can be no liability in damages, however careless the conduct or foreseeable the harm." *532 Madison Ave. Gourmet Foods v. Finlandia Ctr.*, 96 N.Y.2d 280, 289 (N.Y. 2001). That limitation on liability "is necessary to avoid exposing defendants to unlimited liability to an indeterminate class of persons conceivably injured by any negligence in a defendant's act." *Id.* To that end, it is "'the responsibility of the courts in fixing the orbit of duty, to limit the legal consequences of wrongs to a controllable degree and to protect against crushing exposure to liability.'" *McCarthy v. Olin Corp.*, 119 F.3d 148, 157 (2d Cir. 1997) (quoting *Strauss v. Belle Realty Co.*, 65 N.Y.2d 399, 402(N.Y. 1985)).

Here, Plaintiff alleges a duty in tort arising from Microgenics' contract to supply DOCCS with analyzers, immunoassays, and related services.[5] But when a plaintiff premises a negligence claim on a contractual undertaking to someone other than the plaintiff, the general rule is that the undertaking "is ***not*** a source of tort liability to third parties." *Landon v. Kroll Lab. Specialists, Inc.*, 22 N.Y.3d 1, 6 (N.Y. 2013) (emphasis added). As courts in this district have explained, "a

[5] Because Plaintiff says she is "not yet" asserting products-liability claims, Pl.'s Letter to Block, J. [ECF 22] at 3, this memorandum does not address the duties owed by product sellers.

contractual agreement between two parties will rarely create a duty in tort that extends to a non-promisee." *Doona v. OneSource Holdings, Inc.*, 680 F. Supp. 2d 394, 402 (E.D.N.Y. 2010); *accord Nguyen v. Morrison Healthcare*, 412 F. Supp. 3d 196, 202 (E.D.N.Y. 2018) ("Under New York law, 'a contractor generally does not owe an independent duty of care to a non-contracting third party.'" (citing *Guzman v. Wackenhut Corp.*, 394 F. App'x 801, 803 (2d Cir. 2010))).

While the general no-duty rule "is subject to certain exceptions," the New York Court of Appeals has identified only three "narrow circumstances" in which a contractual undertaking gives rise to a duty to third parties. *Santos v. Deanco Servs., Inc.*, 142 A.D. 137, 140 (N.Y. App. Div. 2016). Specifically, a tort duty arises (1) where the contracting party launches a force of harm, (2) where the plaintiff detrimentally relies on the continued performance of the contract party's duties, or (3) where the contracting party has entirely displaced the other party to maintain premises safely. *Espinal v. Melville Snow Contractors*, 98 N.Y.2d 136, 140 (N.Y. 2002).

Plaintiff does not affirmatively plead any of the three so-called "*Espinal* exceptions," but she apparently seeks to invoke the force-of-harm exception, as the others have no colorable application. On the facts alleged, however, the force-of-harm exception does not apply either.

In *Landon v. Kroll Laboratory Specialists, Inc.*, the New York Court of Appeals considered whether a tort duty arises under the *Espinal* force-of-harm exception when a drug-testing *laboratory* enters into a government contract to conduct drug tests on parolee. 22 N.Y.3d 1, 6–7. The plaintiff there alleged that his probation officer required him to provide an oral fluid sample, which was sent to a laboratory for testing. *Landon*, 22 N.Y.3d at 48. The lab generated a report stating that the plaintiff's sample tested positive for THC, *id.*, and although a contemporaneous blood test that the plaintiff independently ordered came back negative, the county probation department commenced violation-of-probation proceedings that extended the plaintiff's probation.

Id. The plaintiff sued the laboratory for negligence, alleging that it violated multiple established industry and government standards for laboratory drug testing, including a federal standard for the test cutoff level, a state standard requiring chromatographic confirmatory testing, and a proposed federal guideline that a urine sample should be taken contemporaneously with an oral sample. *Id.* at 4–5.

Analyzing those allegations in view of the general no-duty rule, a divided Court of Appeals held that the complaint stated a viable claim for relief under the force-of-harm exception. *Landon*, 22 N.Y.3d at 5. Noting that laboratories are "in the best position to prevent false positive results," the court concluded that laboratories owe a tort duty directly to test subjects to conduct tests "***in keeping with relevant professional standards***." *Id.* at 6–7 (emphasis added).

The *Landon* holding does not, however, establish a broad duty running from laboratories or other drug-screen services providers to test subjects. To the contrary, and as the New York Court of Appeals has explained, *Landon* is a "limited ruling." *Pasternack v. Lab. Corp. of Am. Holdings*, 27 N.Y.3d 817, 826 (N.Y. 2016). The tort duty recognized in *Landon* is "limited to 'th[o]se circumstances'" in which a "drug laboratory[ ]" fails to "adhere to professionally accepted scientific testing standards in the testing of the biological sample." *Id.*

Here, Plaintiff asserts that the facts pleaded in her Complaint are "nearly indistinguishable" from *Landon*, Pl.'s Letter to Block, J. [ECF 22] at 3, but on its face, the Complaint fails to state a claim under *Landon* because the facts Plaintiff alleges differ from those at issue in *Landon* in at least two critical and decisive respects.

1. Microgenics is not a "drug laboratory."

First, Microgenics did not provide laboratory drug-test services to DOCCS. It supplied drug-screening equipment and training on how to use the equipment, but the drug screens

themselves were performed by DOCCS personnel. That distinction is dispositive under *Landon*. In choosing to recognize a limited tort duty as to drug laboratories, the New York Court of Appeals emphasized that a drug-testing laboratory is "in the best position to prevent false positive results." 999 N.E.2d at 679. The same cannot plausibly be said about a contractor that supplies products and equipment for in-house urinalysis drug screens but that does not obtain the urine sample, store the urine sample, or process the urine sample—and that does not have continuous possession of, or even access to, the analyzers, immunoassays, and other products used to conduct the screens.

Plaintiff argues that, as an equipment supplier, Microgenics is "the equivalent of a lab." Pl.'s Letter to Block, J. [ECF 22] at 2. That contention does not withstand scrutiny. Microgenics supplies equipment *used* in laboratories but is not itself a laboratory. *See* N.Y. Pub. Health Law § 571(1) (defining a "clinical laboratory" as a "facility" for certain types of examinations of materials derived from the human body); Compl. ¶ 8 (alleging that Microgenics specializes "in the development, manufacture, marketing, and sale of products relating to clinical diagnostics"). Thus, the duty recognized in *Landon* does not extend to Microgenics.

2. Plaintiff does not allege any "relevant professional standards."

Second, the limited duty recognized in *Landon* is that a laboratory must perform drug tests in keeping with "professionally accepted scientific testing standards." *Pasternack*, 59 N.E.3d at 490. It follows that to pursue a claim under *Landon*, a plaintiff must identify a "statutory, regulatory, or professional standard[ ]" with which the defendant allegedly failed to comply. *Braverman v. Bendiner Schlesinger, Inc.*, 121 A.D.3d 353, 359 (N.Y. Ct. App. 2014).

Here, Plaintiff cites no such standards. Indeed, she does not allege the existence of even a single relevant scientific testing standard. Although the Complaint repeatedly refers to "applicable standards" for Microgenics' analyzers, the only alleged standards that Plaintiff identifies are

Microgenics' admonitions to product users that drug screens by immunoassay generate preliminary analytical results and that more specific alternative chemical methods must be used to obtain confirmed analytical results. Compl. ¶ 34. Those statements from Microgenics' IFUs are not scientific testing *standards* that governed Microgenics' contractual undertaking; they are *descriptions* of the type of products DOCCS chose to purchase—immunoassay drug screens that produce preliminary analytical results that must be confirmed chromatographically.

Plaintiff therefore has not plausibly alleged a relevant professional standard governing Microgenics' contractual obligations to DOCCS, and the Complaint thus fails to state a claim under *Landon*. *See Pasternack*, 27 N.Y.3d at 826 (holding that ministerial standards governing laboratory-test services providers do *not* create tort duties owed directly to third-party test subjects); *Braverman*, 121 A.D.3d at 359 (holding that the plaintiffs had no claim under *Landon* because there were "no professional standards implicated in this case").

In sum, Plaintiff has not alleged facts sufficient to overcome the general no-duty rule set forth in *Espinal*.

B. Even if Plaintiff had alleged an actionable duty, she has not plausibly alleged that Microgenics breached any such duty.

To plead a claim for negligence, a plaintiff "is required to allege . . . 'how the [defendant] was negligent.'" *Farash v. Cont'l Airlines, Inc.*, 337 F. App'x 7, *9 (2d Cir. 2009) (alteration in original) (citing *Patterson v. New York*, 54 A.D.2d 147, 150 (N.Y. App. Div. 1976)). Conclusory allegations of breach do not suffice. *Id.*

Here, Plaintiff vaguely alludes to four alleged breaches of Microgenics' putative tort duty: (i) failing to ensure that the analyzers "yielded accurate and reliable" results; (ii) entering into a contract "for use" of the analyzers that "was inconsistent with applicable standards"; (iii) failing to "train DOCCS employees on applicable standards" for using the analyzers; and (iv) testifying

at disciplinary hearings "when Defendants knew that the results were a preliminary screen only." Compl. ¶ 110. None of those conclusory allegations gives meaningful notice of the manner of breach Plaintiff intends to prove.

The first alleged breach—the bald assertion that Microgenics failed to ensure accurate and reliable results—conveys no information about the conduct Plaintiff claims constitutes negligence. What acts or omissions does Plaintiff contend caused the allegedly inaccurate and unreliable results? Does she allege negligence in manufacturing, marketing, selling, installing, maintaining, or training? Or all of those? In any event, in what way does Plaintiff claim Microgenics acted negligently? The Complaint does not identify any specific flaws in the manufacturing, marketing, selling, installing, maintaining, or training. Nor does Plaintiff allege any facts explaining how hypothetical flaws in the manufacturing, marketing, selling, installing, maintaining, or training could have caused analyzer results that were not "accurate and reliable." To the contrary, Plaintiff admits she has no idea how or why the analyzers supposedly produced incorrect results. *See* Hr'g Tr. [ECF 29] at 47:6–11, Jan. 29, 2020 ("We know that something happened, and that there was a duty that was breached, we're confident. What we don't know is what exactly that was . . . ."). And her barebones allegation that Microgenics failed to ensure accurate results falls far short of the operative pleading requirements. *See, e.g.*, *Pawaroo v. Countrywide Bank,* No. 09–CV–2924 (ARR)(SMG), 2010 WL 1048822, *4 (E.D.N.Y. Mar. 18, 2010) (dismissing negligence claim for failure "to allege with sufficient specificity facts upon which a breach of duty" could be inferred); *cf. Quintana v. B. Braun Med. Inc.*, No. 17-cv-06614, 2018 WL 3559091, at *3 (S.D.N.Y. July 24, 2018) (dismissing a design-defect claim because the complaint did not allege a specific defect).

Plaintiff grounds her remaining alleged breaches in the fact that Microgenics' immunoassay screening generates preliminary results. Compl. ¶¶ 34, 110. She suggests

Microgenics was negligent for selling such a system, that Microgenics failed to train DOCCS about the preliminary nature of the results, and that Microgenics personnel should not have testified[6] about such results at disciplinary hearings. *Id.* Each of those criticisms implies that DOCCS was unaware that the Microgenics drug screens would produce only preliminary analytical results. But it is a matter of public record that DOCCS intentionally chose to rely on preliminary immunoassay drug screens to combat drug abuse in its prisons. It has done so for years. *See Lahey v. Kelly*, 71 N.Y.2d 135, 144 (1987). So the suggestion that Microgenics breached a duty by selling DOCCS a system that generates only preliminary results or by failing to train DOCCS about the preliminary nature of the results is facially implausible. *See, e.g.*, *Barakos v. City of New York*, No. 11CV0007BSJGWG, 2012 WL 13036392, at *2 (S.D.N.Y. Aug. 21, 2012) (noting that plaintiff's allegations were "facially implausible, and thus insufficient to raise a right to relief"). DOCCS purchased the type of screening system it wanted and used the results as it saw fit.

Assuming the truth of her averments and granting her every favorable inference, Plaintiff has not adduced sufficient allegations to state a plausible negligence claim, and her action must be dismissed.

II. Class adjudication is impracticable, and thus the class allegations should be struck.

Rule 12(f) of the Federal Rules of Civil Procedure provides that a court may "strike from a pleading . . . any redundant, immaterial, impertinent, or scandalous matter" sua sponte or "on motion made by a party." Rule 23(c)(1)(A) of the Federal Rules of Civil Procedure "calls for a determination of 'whether to certify the class as a class action' at 'an early practicable time after a person sues . . . as a class representative.'" *Greene v. Gerber Prods. Co.*, 262 F. Supp. 3d 38, 52

[6] As to testifying, Plaintiff does not allege that any Microgenics personnel testified at her disciplinary hearing.

(E.D.N.Y. 2017) (citations omitted). Taken together, those rules empower courts to strike class allegations from a complaint once it becomes clear that those allegations are "untenable." *Rahman v. Smith & Wollensky Rest. Grp., Inc.*, No. 06 Civ 6198 (LAK)(JCF), 2008 WL 161230, at *3 (S.D.N.Y. Jan. 16, 2008).

Although generally disfavored, a motion to strike class allegations at the pleadings stage is eminently proper where the plaintiff's allegations demonstrate "it would be impossible to certify the alleged class regardless of the facts the plaintiffs may be able to obtain during discovery." *Greene*, 262 F. Supp. 3d at 52; *accord Chen-Oster v. Goldman, Sachs & Co.*, 877 F. Supp. 2d 113, 120–22 (S.D.N.Y. 2012) (granting defendant's motion to strike class allegations at pleadings stage where class certification would fail as a matter of law); *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 949 (6th Cir. 2011) (affirming striking of class allegations where no type of factual development would cure the central defect in class claim); *Cook Cty. Coll. Teachers Union Local 1600, Am. Fed'n of Teachers, AFL-CIO v. Byrd*, 456 F.2d 882, 884 (7th Cir. 1972) (affirming dismissal of class claims before discovery and on the pleadings).

Here, despite her amendments, Plaintiff's class allegations present a host of insurmountable obstacles to certification—the same types of obstacles that have led dozens of courts either to deny certification or strike class allegations at the pleadings stage. *First*, Plaintiff's proposed class is so broad as to encompass persons who lack standing to sue. *Second*, it is facially apparent that litigation of the proposed class members' claims—as to liability and damages—would turn on highly individualized factual questions that destroy any semblance of the commonality or predominance required to sustain the alleged class. And it is equally apparent that no amount of discovery will cure those infirmities. Rather than permitting Plaintiff to litigate under the specter of classwide adjudication, the Court should strike the class allegations at the outset.

A. Plaintiff's proposed class fails as a matter of law because it is so broadly defined as to include persons who received accurate drug screens and thus lack standing.

The threshold question of standing centers on "whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). To meet the Article III standing requirement, a plaintiff must have suffered an "injury in fact" that is "distinct and palpable"; the injury must be fairly traceable to the challenged action; and the injury must be likely redressable by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Further, the "injury in fact" must be "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Weisenberg v. Town Bd. of Shelter Island*, 404 F. Supp. 3d 720, 726 (E.D.N.Y. 2019). The plaintiff bears the burden to clearly allege facts supporting each element. *Id.* (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016)).

It is well-established that "no class may be certified that contains members lacking Article III standing." *Denney v. Deutsche Bank AG*, 443 F.3d 253, 264 (2d Cir. 2006); *see Adashuna v. Negley*, 626 F.2d 600, 604 (7th Cir. 1980) (affirming the denial of a plaintiff class because the definition was "so amorphous and diverse" that it was not "reasonably clear that the proposed class members have all suffered a constitutional or statutory violation warranting some relief"). Accordingly, any proposed class must be defined in such a way that anyone within it would have standing. *Denney*, 443 F.3d at 264. Otherwise, the class claims fail as a matter of law and may be struck at the pleadings stage. *Chen-Oster v. Goldman, Sachs & Co.*, 877 F. Supp. 2d 113, 120 (S.D.N.Y. 2012).

Plaintiff's Complaint defines the proposed class as consisting of "all persons subjected to the Defendants' unreliable testing devices and services provided under the contract and who received positive drug test results generated by Indiko Plus urinalysis analyzers while in DOCCS custody in 2019 and subsequently had those positive drug tests reversed." Compl. ¶ 95. That overly

broad definition makes no distinction between persons who allegedly received so-called "false positive" results, and those who received correctly-identified true positive results. Any persons who received true positive results have no injury, and absent an "injury in fact," such persons lack standing to sue. *See Presbyterian Church of Sudan v. Talisman Energy, Inc.*, 244 F. Supp. 2d 289, 334 (S.D N.Y. 2003) ("[E]ach member of the class must have standing with respect to injuries suffered as a result of defendants' actions.").

Plaintiff bears the burden to plead clear facts establishing each element of standing. *Weisenberg,* 404 F. Supp. 3d at 726. She has failed to do so. Instead, Plaintiff implausibly implies that *all* positive results derived from Indiko Plus urinalysis analyzers and subsequently reversed by DOCCS were false. Compl. ¶¶ 46–47, 88. She pleaded no facts to support such a sweeping conclusion, however, and the Court should disregard it. *See Premium Mortg. Corp. v. Equifax, Inc.*, 583 F.3d 103, 108 (2d Cir. 2009) ("The complaint presents only conclusory allegations as to this element, and we find them facially implausible."). The mere fact that DOCCS reversed any given result does not in itself support the implausible inference sought by Plaintiff, that *all* positive results reversed by DOCCS were also false positives. Indeed, Plaintiff pleaded no facts to indicate that DOCCS's blanket reversal decision was based on any distinction or identification between false positive and true positive results. Absent such determination, Plaintiff offers nothing more than her own conjecture that all results encompassed by DOCCS's reversal decision were false positive results.

Without factual content plausibly suggesting that *every* positive result was false, Plaintiff's proposed class definition incorporates persons who sustained no injury and lack standing, and Plaintiff's class allegations therefore fail as a matter of law. *See Denney,* 443 F.3d at 264 ("[N]o

class may be certified that contains members lacking Article III standing."). For those reasons, Plaintiff's class action claims should be properly struck for lack of standing.

B. Regardless, no class could be certified because the putative class members' claims are inherently individual and necessitate plaintiff-specific fact-finding.

Lack of standing is not the only facial deficiency in Plaintiff's class-action claims as they additionally lack the requisite commonality and predominance of common questions necessary for class certification. No additional discovery can salvage Plaintiff's class-action claims as the individualized inquiries necessary to distinguish false positives from true positives undermine any alleged predominance of common factual questions within the class. In addition, the voluminous number of other individualized factual questions required to resolve the claims at issue render class action a wholly inappropriate vehicle for their resolution.

A class action is an exception to the rule that litigation be conducted by and on behalf of the named parties. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011). As in *Dukes*, Plaintiff's proposed class lacks the commonality required by Rule 23(a). *See id.* at 349.[7] Commonality means more than simply naming at least one issue of law or fact common to the class, which is virtually always possible at a high level of generality. Instead, as *Dukes* explained, commonality means that class members' claims depend upon a common contention "of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Id.* at 350. In other words, "[w]hat matters to class certification . . . is not the raising of common 'questions'—even in droves—but rather the capacity of a classwide proceeding to generate common *answers* apt to drive the resolution of the litigation." *Id.*

[7] Microgenics does not concede and reserves argument as to Rule 23(a)'s other requirements.

In addition to commonality, Rule 23(b)(3) further requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members." The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation. *Amchem Prods., Inc. v. Windsor,* 521 U.S. 591, 623 (1997). Even where a common question may be found, "the predominance criterion is far more demanding." *Id.* at 623–24. A class is properly dismissed for lack of predominance where the class action mechanism would achieve no "economies of time, effort, and expense." *See Enriquez v. Cherry Hill Mkt. Corp.*, 993 F. Supp. 2d 229, 235–36 (E.D.N.Y. 2014) (denying certification where each class member would have to establish independent details of underpaid wages and defendant would be entitled to contest each member's claims). Class treatment is therefore improper where extensive individual questions would result in a mini-trial on each class member's claims. *Enriquez*, 993 F. Supp. 2d at 235–36.

In light of those requirements, Plaintiff's claims cannot possibly generate the requisite predominance of "common answers." Even assuming some degree of common questions exist generally as to duty or breach, an assumption Microgenics denies, any such commonality is surpassed by the myriad individualized questions required to establish multiple elements of Plaintiff's claims. Specifically, every class member will require individualized questions regarding whether he or she actually received a false positive result (i.e., an actual injury), the causal relation between any alleged conduct of Microgenics and any actual injury, and the specific circumstances and basis behind each class member's independent disciplinary action, if any.

At the outset, every individual class member will require specific factual inquiries as to whether each putative class member actually received a false positive result. Whether each putative class member received a false positive result, as opposed to an accurate true positive result, would

be a fundamental threshold question—one not susceptible to class adjudication. More than simply a question of standing or damages, the existence, or lack thereof, of a false positive screening result cuts to the heart of any alleged liability. The mere fact that a class member underwent drug screening using the Indiko Plus urinalysis analyzer does not in and of itself create an actionable injury. Nor, contrary to Plaintiff's overbroad class definition, does the reversal of disciplinary action establish a recoverable injury. If the drug screening was accurate in identifying an inmate's drug use, the inmate sustained no injury. Based on the allegations in the Complaint, that inquiry will require specific, individual factual findings based on each putative class member's medications, diet, preceding conduct prior to testing, and potentially even their physical interactions with others.[8] Far from a de minimis inquiry, such findings will be required for *every* class member to establish the foundational element of each claim, an actual injury.

Indeed, Plaintiff's own pleading demonstrates the necessity of individualized inquiries into each and every class member's case-specific details. In her Complaint, Plaintiff averred that "she did not ingest any substances containing suboxone/buprenorphine" and that "she submitted medical documents from her husband's doctor explaining that the false positive may have been triggered by a medication he had been prescribed." Compl. ¶ 77. Those contentions, apparently offered to support Plaintiff's individual claim that her positive screening result was inaccurate, demonstrate the need for independent investigations for every putative class member in order to determine the relative accuracy of each individual's screening result. *Cf.* 7 NYCRR § 1020.4(d)(2) (requiring DOCCS to make an "inquiry . . . to medical personnel as to what medications the inmate

[8] Plaintiff refers to medical documents submitted by her husband's doctor explaining a possible false positive result may have been triggered by a medication he prescribed (to her husband). Compl. ¶ 77. Her contention appears to be that her positive test result was due to some degree of cross-reactivity with substances she came into contact with during the time spent with her husband.

has received in the past month which may lead to a positive result" for any inmate who has confirmed taking medication in the month prior to receiving a positive drug screening result). Such inquiries would require the fact-finder to weigh the individual evidence for each putative class member to assess each individual's claim of an inaccurate drug screen.

Causation too is uniquely specific to each class member and would necessitate individualized inquiries. Plaintiff's claims encompass urinalysis analyzers at fifty-two different correctional facilities, Compl. ¶ 22, each of which invariably will have its own staff, site-specific policies, and facility-specific circumstances. Further fracturing any semblance of commonality, Plaintiff's claims encompass at least four separate immunoassays testing for four different substances, Suboxone/buprenorphine, AB Pinaca, opiates, and THC. Compl. ¶¶ 43, 46. Each assay is a discrete product with a different design, different specifications, and different instructions for use. Evaluating what procedures were followed by DOCCS officers for each screening, at what facilities, and what machines and particular assays were used for each screening (and the specific maintenance provided for each) all require highly individualized assessments of the circumstances, individual products, facilities, and personnel encountered by each putative class member.

Individual questions of proximate causation pervade every claim as any alleged error in individual screening results may have just as easily resulted from errors by individual DOCCS personnel, whether in collecting the sample, preserving the sample, or testing the sample, and any such errors may further vary from one instance to the next. *See Jones v. BRG Sports, Inc*., No. 18 7250, 2019 WL 355374, at *6 (N.D. Ill. Aug. 1, 2019) (striking class allegations due to predominating individualized issues of law and fact and noting that products claims for personal injuries require that each plaintiff "will necessarily need to prove causation and injury"); *In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 241 F.R.D. 435, 449 (S.D.N.Y. 2007)

(denying certification for proposed class in personal injury, toxic tort claim where "the disparities in the injuries, and the questions of whether the gasoline caused such injuries," were "too great"). Indeed, the fact-finder here would have to evaluate each class member individually to determine—among myriad other issues—if the urinalysis analyzers actually contributed in any way to each alleged false positive result in light of potential procedural errors by DOCCS in collecting and storing the samples, even before any such samples are ever introduced to the analyzer. The long chain of causation, from collection, identification, testing, and resolution based on test results, contains numerous other potential causes that a fact-finder would need to individually assess before reaching any conclusion as to the causative role of any Indiko Plus urinalysis analyzer.

The fact-finder would also have to determine what difference, if any, "better" training or "precautions" on Microgenics' part would have made to any specific procedural errors related to each inmate's testing sample and results. Any allegation that training or precautions, or lack thereof, contributed to an individual class member's alleged false-positive result necessarily entails the threshold questions of what specific procedural errors, if any, occurred and whether such errors were due to lack of training and precautions or DOCCS personnel's independent failure to follow the training and precautions already provided by Microgenics. *Cf. Medina v. Biro Mfg. Co.*, 151 A.D.3d 535, 536 (N.Y. App. Div. 2017) (ruling servicer of meat-cutting bandsaw cannot be held liable to injured plaintiff for negligent performance of the contract absent "any connection between any service it provided and plaintiff's accident"); *Attanasio by Attanasio v. Attanasio*, 126 A.D.2d 812, 813 (N.Y. App. Div. 1987) (granting summary judgment where sole cause of plaintiff's injury from gardening shear was not attributable to any alleged failure to instruct on proper use of the tool). Those questions are individual to specific class members, as different alleged errors raise case-specific questions as to what training or precautions, if any, were negligent, and may differ

greatly from one case to the next. Far from a de minimis issue, those questions cut to the core issue of proximate causation as to claims of negligent training and inadequate precautions.

Even if those threshold factual questions were resolved, it is facially apparent that any disciplinary action would further entail overwhelming individual questions regarding the particular circumstances prompting each class member's drug screening, their previous record of behavior, and other circumstantial considerations regarding the facility where the class member was disciplined. The State of New York's own regulations governing DOCCS disciplinary policies emphasize the individualized considerations behind each disciplinary decision, including such factors as (1) the particular circumstances involved, (2) the overall behavior pattern of the inmate, and (3) the problems in and the present atmosphere of the facility. 7 NYCRR 250.2(b). Those highly particularized considerations obliterate any semblance of "common answers" as putative class members undeniably experienced different proceedings, outcomes, and factual circumstances underlying their individual disciplinary actions. *See Moore v. PaineWebber, Inc.*, 306 F.3d 1247, 1255–56 (2d Cir. 2002) (denying certification where defendant's alleged misrepresentations, and putative class members potential reliance on the same, "varied dramatically"). The initial basis for disciplinary action, the specific nature of discipline administered, each class member's evidence as presented in rebuttal (or even whether a given class member actually opposed the findings), all of the issues pose case-specific questions reveal wide potential variation in the scope of alleged harm and damages among individual class members.

The above infirmities are exactly why mass tort claims are "ordinarily not appropriate for class treatment," as they present "significant questions . . . affecting the individuals in different ways." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (citations omitted). Where, as here, individual factual questions related to proximate causation and the nature of class members'

specific injuries override any common questions, a class action cannot proceed, and dismissal of such class allegations is proper. *See In re MTBE,* 241 F.R.D. at 449 (denying certification as common questions did not predominate where nature of alleged tortious exposure and resulting injuries required highly individualized inquiries). Those innumerable individualities are a "key reality" that "no proffered or potential factual development offers any hope of altering." *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 949 (6th Cir. 2011). Thus, they warrant striking Plaintiff's class allegations at the outset. *See Chen-Oster v. Goldman, Sachs & Co.*, 877 F. Supp. 2d 113 (S.D.N.Y. 2012) (granting defendant's motion to strike class allegations at pleadings stage where class certification would fail as a matter of law).

Conclusion

For all the reasons stated, Defendant Microgenics Corporation respectfully requests that the Court grant its motion to dismiss the Complaint and strike Plaintiff's class allegations.

Respectfully submitted,

s/Christopher R. Carton

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